

lives. Dr. Stein's company is one of many across the United States working to prevent infections and improve American's quality of life.

ANTIBIOTICS REDUX: MEDICINES THAT CHANGE THE COURSE OF HISTORY

DATELINE: APRIL 1945. HILL 913, NORTHERN ITALY

The 22-year old second lieutenant didn't know if it was the machine gun, mortar round or artillery shell blast that got him. Ordered to take out the machine gun nest hidden in a mountaintop farmhouse all he recalled was that he was dragging his platoon's wounded radio operator to safety when he felt a searing pain in his upper back, then nothing. The platoon medic took one look at the wounded lieutenant, injected him with the maximum survivable dose of morphine, indicating this by marking the letter "M" on his forehead in his blood, then, assuming he would not survive his wounds, left to treat other wounded platoon members. Although his initial wounds, which included a damaged spine, an obliterated kidney and a mangled right arm did not kill him outright, the lieutenant was shipped home with little expectation he'd survive. His parents were called to his hospital bedside three separate times for a death vigil.

APRIL 1945. RUTGERS UNIVERSITY

Four-thousand miles west of Hill 913, 25-year-old graduate student Albert Schatz, having recently submitted his patent application for his discovery of the antibiotic Streptomycin, was trying to figure out how to make enough of it for human testing. Tests in guinea pigs showed that Streptomycin was safe and effective in the treatment of infections caused by gram-negative bacteria and *Mycobacterium tuberculosis*. What motivated Schatz was that in the first half of the century bacterial infections—pneumonia, tuberculosis and blood stream infections—were the top three causes of death in the U.S. Wounded servicemen from World War II were especially prone to infections from gram-negative bacteria and the only other widely available antibiotic at the time, penicillin, was largely ineffective against these pathogens. As a child Schatz had experienced close friends dying of tuberculosis and as a medical bacteriologist stationed in an Army hospital in Florida during the early years of World War II, Private Schatz sat helplessly by the bedside of dying soldiers whose infections did not respond to penicillin or the experimental antibiotics then available. He was passionate and highly committed. Schatz produced Streptomycin from the soil bacterium *Streptomyces griseus* growing in 1-liter fermentation flasks running 24-hours a day in his basement laboratory at Rutgers. By the end of 1945 he had produced what he believed to be enough to treat one patient.

MARCH 1946. PERCY JONES ARMY HOSPITAL, BATTLE CREEK, MICHIGAN

The attending doctors had virtually encased the lieutenant's body in ice in a desperate attempt to lower his body temperature. His weakened immune system made him susceptible to infection and he had developed a severe lung infection that subsequently spread to his blood with resultant high fever. Massive doses of penicillin were ineffective. He was dying. Word of his condition made its way to Rutgers and Albert Schatz who subsequently rushed the first experimental dose of Streptomycin to Percy Jones Hospital to treat the lieutenant. The effects were nothing short of miraculous. The lieutenant's fever broke within 24 hours and his lung infection cleared within a week. He would survive. Later that year Streptomycin would go on to become the world's

first experimental medicine to be tested in a double blind, placebo controlled clinical trial—the gold standard in clinical research—where it was shown to be effective and safe for the treatment of TB.

The lieutenant's name? Bob Dole. Yes, that Bob Dole who would go on to become Senate Majority Leader and, in 1996, candidate for the Presidency of the United States.

TODAY.

What is instructive about this true story of how an antibiotic altered the course of history is that we are presently on a retrograde course back to the early 20th century with respect to the treatment of bacterial infections. In the five-year period from 1983 to 1987 there were 16 new antibiotics approved, whereas from 2008 to 2012 there were only two. At the same time, there is an explosive emergence of multidrug resistant bacteria that are rendering existing antibiotics largely ineffective. Combat veterans returning from the Middle East have been diagnosed with drug resistant strains of the gram-negative pathogen *Acinetobacter baumannii* for which there are virtually no treatment options. The multidrug resistant NDM-1 strain of *Klebsiella pneumoniae*, which initially emerged from India, has spread globally. One in three people in the world are infected with a dormant version of *Mycobacterium tuberculosis* and a growing number of these, reported in 60 countries, have emerged as the highly virulent XDR-TB strain which is resistant to both first- and second-line TB therapies and can only be treated with a multiyear regimen of toxic drugs. Indeed, today's situation would likely ignite the same sense of urgency in Albert Schatz that he felt in 1945.

Fortunately, we have passionate and committed contemporary versions of Albert Schatz working to develop new antibiotics. Because of the enormous capital requirements and complex regulatory pathway for antibiotics, however, these individuals are now largely found in small biotech companies where the truly innovative antibiotics are currently being developed. It is unclear which, if any, of these companies will succeed in delivering critically needed medicines to the market. As drug resistant bacterial pathogens continue to proliferate, regulatory headwinds and market dynamics have made antibiotic development extremely challenging. While it is encouraging that this disconnect is receiving growing recognition and action amongst regulatory authorities, these small antibiotics companies, such as Trius Therapeutics where I am CEO, wait to see whether these regulatory incentives, such as the GAIN Act recently passed by Congress, can be implemented in time to make the development of new antibiotics clinically feasible and financially tractable. It will certainly be a race in which the outcome could alter the course of history and yes, save lives.

PERSONAL EXPLANATION

HON. MIKE PENCE

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Monday, December 31, 2012

Mr. PENCE. Mr. Speaker, I was unavoidably absent on December 30, 2012 and missed rollcall votes 649 through 651. Had I been present, I would have voted "aye" on rollcall votes 649, 650, and 651.

RECOGNIZING THE LIFE OF ELIZABETH COX

HON. LEONARD LANCE

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Monday, December 31, 2012

Mr. LANCE. Mr. Speaker, I rise today to honor the life of Elizabeth Cox of Summit, New Jersey. Betty gave her life to public service in New Jersey and her contributions will long be remembered.

Betty was elected to the New Jersey General Assembly in 1972 to serve an unexpired term. Betty would continue four decades of public service as a founding member of the Women's Political Caucus, as a master poll worker for the Union County Board of Elections, as a staff member in the Department of Community Affairs and as an officer in the Summit, Union County and New Jersey Republican Committees.

Betty will be remembered as a dedicated public servant, a parliamentarian and a champion of women's issues. I was honored to call Betty a friend and colleague.

PAUL KRUGMAN AND THE ECONOMIC CASE FOR FAIRNESS

HON. BARNEY FRANK

OF MASSACHUSETTS

IN THE HOUSE OF REPRESENTATIVES

Monday, December 31, 2012

Mr. FRANK of Massachusetts. Mr. Speaker, Paul Krugman has consistently and articulately defended programs that are essential for the quality of life for our most vulnerable residents, and exposed the flawed morality and impaired logic of those who seek to use the existence of a large national debt as an argument for exacerbating inequality in the United States. His column for Monday, December 31 is an excellent example of this, and I hope all Members will pay attention to its message.

BREWING UP CONFUSION

(By Paul Krugman)

Howard Schultz, the C.E.O. of Starbucks, has a reputation as a good guy, a man who supports worthy causes. And he presumably thought he would add to that reputation when he posted an open letter urging his employees to promote fiscal bipartisanship by writing "Come together" on coffee cups.

In reality, however, all he did was make himself part of the problem. And his letter was actually a very good illustration of the forces that created the current mess.

In the letter, Mr. Schultz warned that elected officials "have been unable to come together and compromise to solve the tremendously important, time-sensitive issue to fix the national debt," and suggested that readers further inform themselves at the Web site of the organization Fix the Debt. Let's parse that, shall we?

First of all, it's true that we face a time-sensitive issue in the form of the fiscal cliff: unless a deal is reached, we will soon experience a combination of tax increases and spending cuts that might push the nation back into recession. But that prospect doesn't reflect a failure to "fix the debt" by reducing the budget deficit—on the contrary, the danger is that we'll cut the deficit too fast.

How could someone as well connected as Mr. Schultz get such a basic point wrong? By